17-1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/044,696	03/18/1998	GAIL BARCHFELD	1393.002	8826

27476 7590 04/29/2004

Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	**Application No.** 09/044,696	**Applicant(s)** BARCHFELD ET AL.	
	Examiner S. Devi, Ph.D.	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *three* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Attachment.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *19 and 25-36*.

   Claim(s) objected to: _____.

   Claim(s) rejected: *37-39 and 41-43*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

ATTACHMENT TO ADVISORY ACTION

After-Final Amendment

1) Acknowledgment is made of Applicants' after-final amendment filed 04/12/04 in response to the final Office Action mailed 01/20/04.

Status of Claims

2) Claims 32, 36 and 37 have been amended via the amendment filed 04/12/04.

Claims 1-18 and 40 has been canceled via the amendment filed 04/12/04.

Claims 19, 25-39 and 41-43 are pending and are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

5) The objection to the specification made under 35 U.S.C. § 132 in paragraph 8 of the Office Action mailed 10/22/02 (paper no. 34) and maintained in paragraph 7 of the Office Action mailed 01/20/04 with regard to the addition of new matter to the specification is maintained for reasons set forth therein and herebelow.

Applicants cite M.P.E.P. 2163.07, and *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971) and contend that amendments to the specification do not constitute new matter if they correct an obvious error, where one skilled in the art would recognize the existence of error and the appropriate correction. Applicants submit that the legal determination that sequences can be added or changed without introducing new matter is also sanctioned in instances in which the issue is whether the claims are adequately described by the specification. Applicants point to M.P.E.P 2163 and state that with 'respect to the correction of sequencing errors in applications disclosing nucleic acid and/or amino acid sequences, it is well known that sequencing errors are a

common problem in molecular biology. With this, Applicants assert that it is well settled that the public availability of a correct amino acid sequence at the time of filing is entirely relevant to the question of whether submission of a known sequence constitutes the addition of new matter. Applicants state that in the pending case, the submission of Figure 3 does not constitute new matter, instead Figure 3 provides a wild type LT-A sequence that corrects obvious errors in many published sequences. Applicants submit that the pre-filing date existence of a GenBank entry corresponding to FIG. 3 clearly establishes that Applicants are correcting an obvious error that would have been recognized as such by the skilled artisan. Applicants resubmit that there is nothing in the previous amendments that goes beyond the originally filed subject matter and that new matter has not been added.

Applicants' arguments have been carefully considered, but are non-persuasive. As set forth previously, the sequence presented via Figure 3 was **not** a part of the specification, as originally filed. Instead, Figure 1 disclosed an LT containing alanine at residue 72. The sequence from Figure 3 is structurally non-identical to the sequence of Figure 1. If existence of an error has been recognized by Applicants in the LT sequence depicted in Figure 1, Applicants would have requested for correction of such errors with proper evidence to demonstrate that such a correction would not introduce new matter. However, Applicants are not requesting for correction of errors in the sequence of Figure 1. Instead, Applicants have added a new Figure, i.e., Figure 3, which adds a new sequence with a new structure/composition which was **not** a part of the specification, as originally filed. Applicants have previously acknowledged that there are differences between the sequences presented originally and those in Figure 3. What was presented via Figure 1, as originally filed, does not provide support for what is now depicted via Figure 3. Whether or not the amino acid sequence of a protein got corrected in the art prior to the invention is not relevant. Whether or not that corrected amino acid sequence was described in the specification as originally filed is the issue that is relevant. The alleged errors in the sequence depicted in Figure 1 can only be corrected by requesting corrections to Figure 1 along with proper evidence, but cannot be resolved by adding a new Figure with a new sequence which was never described or contemplated in the specification, as originally filed. Except for the amino acid sequence depicted in Figure 1, what was publicly known was not a part of the instant

specification, as originally filed. Attempts of bringing in new matter via a new Figure into the specification based on the sequence errors or discrepancies in sequence databases is improper. The objection stands.

Rejection(s) Moot

6) The rejection of claim 40 made in paragraph 12 of the Office Action mailed 01/20/04 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claim.

7) The rejection of claim 40 made in paragraph 13 of the Office Action mailed 01/20/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

8) The rejection of claim 32 and 35 made in paragraph 13(c) of the Office Action mailed 01/20/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the base claim.

Rejection(s) Maintained

9) The rejection of claims 37-39 and 41-43 made in paragraph 12 of the Office Action mailed 01/20/04 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is maintained for reasons set forth therein and herebelow.

Applicants point to page 19, lines 15 and 19-21 of the specification for descriptive support for the recitations: "A antigen.."; "B antigen...."; and "C antigen...". However, these parts of the specification recite 'bacterial antigens derived from' '*Neisseria meningitides* (A,B,C,Y)'. As described in the Dorland's Illustrated Medical Dictionary submitted by Applicants, letters 'A, B, C, Y' stand for serogroups of *Neisseria meningitides* as opposed to 'antigens'. To obviate the rejection, it is suggested that Applicants amend claim 37 as follows:

--37. (currently amended): The method of claim 36, wherein said bacterial antigen is from a bacterium selected from the group consisting of *Bordetella pertussis*, *Helicobacter pylori*, meningococcus A, meningococcus B, and meningococcus C.--

Similar amendments are suggested for claims 41-43.

10) The rejection of claim 37 and 41-43 made in paragraphs 13(a) and 13(b) of the Office Action mailed 01/20/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicants cite case law and contend that the definiteness and clarity of the claim language must be analyzed in light of the content of the particular disclosure, the teachings of the art, and the claim interpretation given by one possessing ordinary skill in the pertinent art at the time the invention was made. Applicants submit the description from the Dorland's Illustrated Medical Dictionary for *N. meningitidis*, which refers to 'A, B, C, D' as serological groups. With this, Applicants assert that when properly read in light of the state of the art, the metes and bounds of the claimed subject matter is more than sufficiently precise.

Applicants' arguments have been carefully considered, but are non-persuasive. As described in the Dorland's Illustrated Medical Dictionary submitted by Applicants, letters 'A, B, C, Y' stand for serogroups of *Neisseria meningitides* as opposed to 'antigens'. To obviate the rejection, it is suggested that Applicants amend claim 37 as follows:

--37. (currently amended): The method of claim 36, wherein said bacterial antigen is from a bacterium selected from the group consisting of *Bordetella pertussis*, *Helicobacter pylori*, meningococcus A, meningococcus B, and meningococcus C.--

Similar amendments are suggested for claims 41-43.

11) The rejection of dependent claims 38 and 39 made in paragraph 13(d) of the Office Action mailed 01/20/04 under 35 U.S.C. §112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

Remarks

12) Claims 37-39 and 41-43 stand rejected. Claims 19 and 25-31 include allowable subject matter. To be consistent with the claim language used in claim 31, in claims 25-30, it is once again suggested that Applicants replace the recitation 'A method according to claim ...' with -- The method according to claim ....--.

13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1.

The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center receives transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

14) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April, 2004

S. DEVI, PH.D.
PRIMARY EXAMINER